

# **EXHIBIT 23**

# DEA Compliance Manual

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# **DEA**

## **COMPLIANCE MANUAL**

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## REQUIRED REPORTS TO DEA

Wholesalers are required to report regularly to DEA's ARCOS Unit all receipts and disposals of all Schedule I and II drugs and Schedule III narcotics. In addition, wholesalers are required to submit other reports to DEA under certain circumstances (e.g., drug thefts, drug destructions and suspicious orders).

### ARCOS Reports

(21 CFR 1304.33)

Every wholesaler who handles controlled substances in Schedule I and II and/or narcotics in Schedule III must report to the ARCOS Unit, as follows:

#### When

Annual Inventory	To be taken on December 31
Initial Inventory	To be taken on the effective date that a substance becomes reportable
Transaction Reporting	Quarterly, or, with DEA permission, monthly

All reports are required to be submitted within 15 days after the end of the report period by certified or registered mail, return receipt requested.

- ARCOS reports sent via commercial carrier such as Federal Express (FedEx), United Parcel Service (UPS) should be sent to:

DEA Headquarters  
Attn: ARCOS Unit  
2401 Jefferson-Davis Highway  
Alexandria, VA 22301

- ARCOS reports sent via the U.S. Postal Service must use the following address:

Drug Enforcement Administration  
ARCOS Unit  
P.O. Box 27273  
Washington, D.C. 20038-7273

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Required Reports to DEA

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Refer to The ARCOS Reporting Manual (Appendix A) for additional information.

### **Optional ARCOS Reporting Modes**

Registrants using punched card accounting machines or electronic data processing equipment should submit either card decks or magnetic tapes. Registrants without automated systems must use the Manual ARCOS OCR Form - DEA Form 333 - (Form #9).

### **Reporting ARCOS Data from Another Location**

For authorization to report ARCOS data from other than a registered location, a central reporting identified must be obtained from the ARCOS unit at the above address.

### **DEA Order Forms**

#### **(21 CFR 1305.09 (d))**

Copy 2 (green) of the order form shall be sent to the local DEA office at the close of the month during which the order was filled. If the order is filled by partial shipments, Copy 2 (green) shall be forwarded at the close of the month during which the final shipment is made or during which the 60-day validity period expires.

### **Drug Thefts/Losses**

#### **(21 CFR 1301.74(c))**

The registrant notifies the DEA field office in that area of any theft or significant loss upon discovery of such theft or loss on **Report of Theft or Loss of Controlled Substances -DEA Form 106- (Form #10)**. Reports must be submitted within seven (7) days of the incident. Reporting in-transit losses is the supplier's responsibility. Reporting responsibility for shipments for which you have a signed receipt lies with the customer.

The reporting of inventory variances on DEA form 106 must be carefully evaluated. The most recent DEA policy addressing this issue reads as follows: "DEA regulations require a registrant to maintain inventory records to track the flow of controlled substances but do not require the maintenance of perpetual inventories. If a firm elects to regularly track inventory balances and notes a theoretical discrepancy, the firm should make every effort to resolve it within a timely manner. If it is determined that an actual discrepancy is the result of a theft or significant loss of controlled drug product, then the nearest DEA field office must be notified immediately upon discovery and the theft or loss must be reported on a DEA Form 106." Variances which are the result of record keeping or order filling errors need not be reported.

Any ARCOS reportable items filed on **DEA Form 106** should also be submitted to ARCOS.

**Note:** Some state agencies require copies of all DEA Forms 106 filed with DEA.

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Required Reports to DEA

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## **Drug Destructions**

### **(21 CFR 1307.21)**

If a wholesaler wants to destroy certain controlled substances (e.g., damaged goods, returns, etc.), the wholesaler should notify the DEA special agent in charge on **Registrant Inventory of Drugs Surrendered - DEA Form 41 - (Form #11)** in triplicate. The special agent in charge will inform the wholesaler how the drug destruction will be handled. Where the wholesaler regularly disposes of controlled substances, the DEA special agent in charge can, upon request, authorize dispositions without prior approval provided that these dispositions are recorded fully and meet all conditions established by the special agent in charge. Destructions of reportable items must be submitted to ARCOS on **ARCOS OCR Form 333**.

*Note: It is DEA's policy that if a state agency having jurisdiction over wholesalers has adopted disposal procedures for controlled substances, the wholesaler may follow these procedures in lieu of DEA requirements.*

Cardinal has a contract with Reverse Management Systems to handle our destruction of unsaleable merchandise. The product is sold to Reverse Management Systems who in turn destroys it and files **DEA Form 41**. Refer to **DEA Correspondence 8/12/94** for additional information.

**DEA Form 41** should also be used for documenting a liquid controlled substance loss when the container accidentally breaks. Any loss of an ARCOS reportable item must also be reported to ARCOS. The pieces of the broken bottle do not need to be retained as evidence of the accident. Refer to **DEA correspondence 11/17/97**.

## **Suspicious Orders**

### **(21 CFR 1301.74(b))**

Wholesalers are responsible for designing and operating a system that will disclose to the wholesaler suspicious orders. The wholesaler informs the DEA field office in that area of all suspicious orders. Suspicious orders include orders of unusual size, orders deviating from a normal pattern and orders of unusual frequency. DEA has no specific form for this.

## **Establishing Suspicious Order Criteria**

Wholesalers should establish **written** criteria of what constitutes a suspicious order. DEA leaves it to the wholesaler to make this determination. The key for the wholesaler is to establish **reasonable** criteria based upon customer purchasing patterns and then to **adhere** to them in monitoring orders. Either a computerized or a manual system can be utilized depending upon the wholesaler's preference and capability.

Complying with 21 CFR 1301.74 (b) is a two-step process. First, each Cardinal Division submits to DEA on a monthly basis an Ingredient Limit Report (Exhibit M). This report is based on a computer program which monitors customer controlled substance purchases for a month and compares these purchases to predetermined averages or limits and if a customer's purchase quantities exceed the established parameters, the customer's activity is printed on the report.

Second, on a daily basis cage and vault personnel should be policing and identifying individual orders that appear excessive in relation to what other customers are buying and/or the customer's purchase history. In these situations, DEA should be notified, if possible, before the order is shipped and a copy of all such orders should be maintained in the division's suspicious order file along with a Regulatory Agency Contact Form (Form #1) noting any specific instructions from DEA.

In an effort to assist cage and vault personnel in identifying these orders, we have developed Dosage Limit Charts (Exhibit P). The products included on these charts are those commonly audited by DEA during their inspections of our facilities and those which have a high potential for diversion. The dosage limits were set by calculating average sales quantities for Knoxville's retail customers and Boston's hospital customer and multiplying by 3 for ARCOS reportable items and 5 for non-ARCOS items.

These charts should be posted in your cage and vault and the hospital and retail dosage limit quantities for particular items should be posted at the product locations.

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Required Reports to DEA

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